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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/816,660 | 03/26/2001 | Stanton B. Dotson | 16517.008 | 8741 |

7590 09/30/2003

Lawrence M. Lavin, Jr.
Monsanto Company
Mail Zone N2NB
800 N. Lindbergh Blvd.
St. Louis, MO 63167

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,660

Applicant(s)

DOTSON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 5, 6, 7, 25, 26, drawn to nucleic acids, classified in class 536, subclass 23.1.
- II. Claims 2-4, drawn to proteins, classified in class 530, subclass 350
- III. Claim 8, drawn to antibodies, classified in class 530, subclass 387.1.
- IV. Claims 9-12, drawn to transformed plants, classified in class 800, subclass 295.
- V. Claims 13-15, 23, 24, 28, drawn to nucleic acid detection methods, classified in class 435, subclass 6.
- VI. Claims 16-22, 27, 29, drawn to methods of producing transgenic plants, classified in class 800, subclass 278.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions in Groups I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the products of each Group differ in structure, function and effect, have different modes of operation, and yield different results. Specifically, the proteins of Group I are polymers composed of amino acids which have specific inhibitory or activating activities based upon their three dimensional folded structure and act to effect the retinoic acid pathway

directly. These molecules can be used for further screening assays or for enzymatic assays on protein function. The nucleic acids of Group II have an entirely different chemical structure, being composed of nucleotides, and operate by hybridization and by serving as a information template. The antibodies of Group III are specific binding molecules which differ in structure and function from both the nucleic acids of Group II and the proteins of Group I since the antibodies function by specific interaction of VDJ domains to specifically interact and detect another molecule. Finally, the transgenic plants of Group IV differ from each of the other Groups because these are entire organisms which display specific phenotypes and specific properties that are distinct structurally and chemically from Groups I-III.

Inventions in Group I and in Groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used for detection methods as in Group V, for nucleic acid purification methods, for DNA sequencing methods, for PCR amplification methods or for transgenic plant synthesis methods of Group VI.

Inventions in Group V and in Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the nucleic acid detection

method is different in mode of operation, function and effect from the transgenic plant synthesis method since the first method results in a detected nucleic acid based upon a hybridization step while the Group VI method results in a transgenic plant based upon transfecting the plant.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Sequence Election

With regard to Groups II-VI, this application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. After selection of one of the Groups above, Applicant is required to also select a restriction subgroup. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

There are 24,143 Restriction subgroups corresponding to SEQ ID NOs: 1-24,143, respectively.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup for prosecution on the merits to which the claims shall be restricted.

ONLY A SINGLE NUCLEOTIDE SEQUENCE WILL BE EXAMINED.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive

unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

With regard to Group I, Claims 25-26 link(s) inventions of SEQ ID NOs: 1-24143. Each SEQ ID NO: represents an independent and distinct invention (unless Applicant clearly admits on the record that each SEQ ID NO: is obvious over one another or shows evidence of this fact). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 25-26.

However, even in the linked claims, Applicant is required to select one specific combination for examination. (See MPEP 803.04). This combination must comprise specific SEQ ID NOs. No other combinations will be examined. Applicant is also requested to identify within the combination, a SEQ ID NO: that is free of the prior art, if possible.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or

divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

A telephone call was made to David Marsh on September 8, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

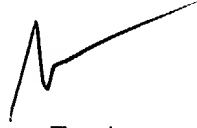
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634